

REMARKS

Claims 41-148 are pending in the present application. Claims 41-54, 70-72 and 74-148 have been withdrawn, leaving claims 55-69 and 73 for consideration in the application. As previously explained, the claims under consideration were copied or substantially copied from claims pending or previously pending in U.S. Application No. 11/334,876.

Anticipation Rejection of Claims 55-65, 69 and 73 over Joseph Jeffrey

In the December 2, 2008 Office Action ("Office Action"), claims 55-65, 69 and 73 were rejected under 35 USC §102(b) as being anticipated by Joseph Jeffrey et al. (WO 97/01986).

Applicants respectfully submit that Joseph Jeffrey cannot anticipate claim 55 because Joseph Jeffrey fails to disclose or suggest at least two significant features recited in Applicants' claim 55. First, Joseph Jeffrey fails to disclose or suggest a receiver which comprises the combination of "a single point glucose monitor," a processor, and computer readable memory with "instructions configured to cause the processor to calibrate the data stream using the glucose concentration measured by the single point glucose monitor." The Office Action relies on Figure 18a of Joseph Jeffrey for disclosure of a single point glucose monitor. Joseph Jeffrey describes Figure 18a as "an illustration of an **extracorporeal** calibration and communication module unit for use in connection with implantable blood constituent sensor modules according to the invention" (page 15 lines 16-18 (emphasis added)) which produces calibration data "by commercially available methods such as glucose oxidase reagent strips 420" (page 34 lines 24-26). Joseph Jeffrey further explains that "[t]he extracorporeal calibration and communication module 410 communicates calibration data directly to **the implanted control module 300**" (Page 34 lines 21-22 (emphases added).) Thus, Joseph Jeffrey discloses an external calibration unit which may accept glucose oxidase reagent strips and which may communicate calibration data to an **implanted** control module.

Nowhere does Joseph Jeffrey disclose a receiver comprising a single point glucose monitor **that also performs the calibration of the data stream**. Even if the calibration unit of Joseph Jeffrey can be characterized as a single point glucose monitor, it is a device that exists separately and externally to the implanted sensor assembly and control module described in Joseph Jeffrey. And it is the implanted sensor and control module which Joseph Jeffrey describes as performing the calibration:

The extracorporeal calibration and communication module 410 communicates calibration data directly to the implanted control module 300 **allowing precise calibration of the measurements made by the control module 300 and its sensor 330.**" (Page 34 lines 21-24 (emphases added).)

The calibration and communication module of Joseph Jeffrey may serve as a conduit for providing calibration data to an implanted control module, but it does not function to calibrate the data stream produced by a glucose sensor.

The second significant feature of claim 55 which Joseph Jeffrey fails to disclose or suggest is computer readable memory comprising "instructions configured to cause the processor to determine a rate of change of the data stream from the substantially continuous analyte sensor." The Office Action relies on Figure 13d of Joseph Jeffrey for disclosure of this feature. Figure 13d is a graph which Joseph Jeffrey describes as illustrating "a plethysmograph of a plurality of pulse waves through a vascular membrane at a specific rate" (Page 14 lines 28-29). Joseph Jeffrey also explains that:

Stroke volume can be estimated by analyzing the plethysmograph pulse wave illustrated in Figure 13d including the maximum amplitude, the area under the curve, the rate of upstroke, and the velocity of wave propagation according to standard processing techniques.

(Page 24 lines 22-25.) Joseph Jeffrey defines "stroke volume" as "the amount of blood ejected with each beat of the heart" (Page 24 line 17.) Thus, Figure 13d illustrates a graph which may be used to estimate the amount of blood ejected with each beat of the heart.

While Figure 13d and the associated text in Joseph Jeffrey may teach a methodology for analyzing data, Applicants respectfully submit that it does not teach that such methodology is embodied in processor instructions contained in the computer readable memory of a receiver, where that receiver also comprises a single point glucose monitor. Even if the methodology were embodied in processor instructions in such a receiver, Applicants submit that estimating the amount of blood ejected with each heartbeat is not the same as determining "a rate of change of the data stream from the substantially continuous analyte sensor," as is recited in Applicants' claim 55. In other words, Joseph Jeffrey teaches a methodology for measuring a volume of fluid flow, not for measuring a **rate of change** of a data stream. Finally, the "data stream" of claim 55 is produced by a glucose sensor and is "indicative of a glucose concentration in a host". Figure 13d of Joseph Jeffrey pertains to measurements indicative of the volume of blood ejected from the heart -- not to measurements of glucose concentration. For each of the above reasons, Joseph Jeffrey fails to disclose or suggest computer readable memory comprising "instructions configured to cause the processor to determine a rate of change of the data stream from the substantially continuous analyte sensor."

Absent any disclosure or suggestion of (1) a receiver comprising the combination of a single point glucose monitor and a processor with instructions to calibrate a data stream or (2) computer readable memory containing instructions configured to cause a processor to determine a rate of change of a data stream from a glucose sensor, Joseph Jeffrey cannot anticipate claim 55. Applicants therefore submit that claim 55 is patentable over Joseph Jeffrey. Applicants also submit that claims 56-69 and 73, which ultimately depend from and include all of the limitations of claim 55, are patentable over Joseph Jeffrey.

Obviousness Rejection of Claims 66-68 over Joseph Jeffrey et al. in view of B. Aussedat

In the December 2, 2008 Office Action, claims 66-68 were rejected for obviousness under 35 USC §103(a) over Joseph Jeffrey, in view of B. Aussedat, "A User-Friendly Method For Calibrating a Subcutaneous Glucose Sensor-Based Hypoglycaemic Alarm," *Biosensors & Bioelectronics*, Vol. 12 No. 11 (1997).

Claims 66-68 depend ultimately from and include all the limitations of independent claim 55, which has been shown to be patentable above. Applicants respectfully submit that claims 66-68 are thus patentable at least by virtue of their ultimate dependency from claim 55.

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Although the Office Action makes various statements regarding claims 55-69 and 73 and the cited references that are now moot in light of the above, Applicants expressly reserve the right to challenge such statements in the future should the need arise (for example, if such statement(s) become relevant by appearing in a rejection of any current or future claim).

In view of the foregoing amendments and remarks, Applicants submit that claims 55-69 and 73 are allowable. The Examiner is invited to telephone the Applicants' undersigned attorney at (312) 775-8197, if any unresolved matters remain.

Please charge any fees incurred in connection with this submission to Deposit Account No. 13-0017.

Respectfully submitted,

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